USSN: 10/737,144 Atty Dkt: DURE-050

PATENT

COMPLETE LISTING OF THE CLAIMS

1. (Previously Amended) An oral dosage form comprising:

a formulation that, upon exposure to an aqueous environment, forms a network within the formulation and an outer surface, wherein the formulation comprises a drug; a high viscosity liquid carrier material (HVLCM); a network former; a rheology modifier; and a solvent.

- 2. (Previously Amended) The dosage form of claim 1, wherein the outer surface, or the network, or both, at least in part result from the interaction between the network former and an aqueous environment.
- 3. (Cancelled)
- 4. (Previously Amended) The dosage form of claim 1, wherein the outer surface, or the network, or both, at least in part result from the interaction between the network former and the HVLCM.
- 5. (Previously Amended) The dosage form of Claim 1 wherein the HVLCM is sucrose acetate isobutyrate (SAIB).
- 6. (Original) The dosage form of Claim 2 wherein the network former comprises a polymer.
- 7. (Previously Amended) The dosage form of Claim 6 wherein the network former comprises cellulose acetate butyrate (CAB).
- 8. (Original) The dosage form of Claim 7 wherein the network former is a CAB having butyryl contents ranging from about 17% to about 38%, acetyl contents ranging from about 13% to about 30%, hydroxyl contents ranging from about 0.8% to about 1.7%, or a combination thereof.
- 9. (Cancelled)
- 10. (Previously Amended) The dosage form of Claim 1 wherein the rheology modifier has a logarithm octanol-water partition coefficient of -7 to +15.
- 11. (Previously Amended) The dosage form of Claim 10 wherein the rheology modifier has a logarithm octanol-water partition coefficient of -1 to +7.
- 12. (Previously Amended) The dosage form of Claim 10 wherein the rheology modifier is selected from the group consisting of caprylic/capric triglyceride (Migliol

USSN: 10/737,144 Atty Dkt: DURE-050

PATENT

810), isopropyl myristate (IPM), ethyl oleate, triethyl citrate, dimethyl phthalate, and benzyl benzoate.

- 13. (Original) The dosage form of Claim 1 wherein the formulation is contained in a capsule.
- 14. (Original) The dosage form of Claim 13 wherein the capsule is a gelatin capsule.
- 15. (Original) The dosage form of Claim 13 wherein the capsule is a hard gelatin capsule.
- 16. (Original) The dosage form of Claim 13 wherein the capsule is a soft gelatin capsule.
- 17. (Original) The dosage form of Claim 1 wherein the formulation further comprises a stabilizer.
- 18. (Original) The dosage form of Claim 17 wherein the stabilizer is an antioxidant.
- 19. (Previously Amended) The dosage form of Claim 1 wherein the HVLCM is present in an amount from about 20 % to 99% by weight.
- 20. (Previously Amended) The dosage form of Claim 19 wherein the HVLCM is present in an amount from about 30% to 90% by weight.
- 21. (Previously Amended) The dosage form of Claim 20 wherein the HVLCM is present in an amount from about 40% to 80% by weight.
- 22. (Previously Amended) The dosage form of Claim 21 wherein the HVLCM is present in an amount from about 50% to 70% by weight.
- 23. (Previously Amended) The dosage form of Claim 1 wherein the rheology modifier is present in an amount from about 0.1% to 10% by weight.
- 24. (Original) The dosage form of Claim 23 wherein the rheology modifier is present in an amount from about 0.5% to 5% by weight.
- 25. (Original) The dosage form of Claim 24 wherein the rheology modifier is present in an amount from about 1% to 4% by weight.
- 26. (Original) The dosage form of Claim 1 wherein the network former is present in an amount less than about 20% by weight of the dosage form.

27. (Original) The dosage form of Claim 26 wherein the network former is present in an amount from about 0.1% to 10% by weight.

- 28. (Original) The dosage form of Claim 27 wherein the network former is present in an amount from about 0.5% to 9% by weight.
- 29. (Previously Amended) The dosage form of Claim 1 wherein the drug is an opioid.
- 30. (Original) The dosage form of Claim 29 wherein the opioid is selected from the group consisting of morphine, methadone, etorphine, levorphanol, fentanyl, sufentanil, a fentanyl related drug, DAMGO, butorphanol, buprenorphine, naloxone, naltrexone, CTOP, diprenorphine, β -funaltrexamine, naloxonazine, nalorphine, pentazocine, nalbuphine, naloxone benzoylhydrazone, bremazocine, ethylketocyclazocine, U50,488, U69,593, spiradoline, nor-binaltorphimine, naltrindole, DPDPE, [D-Ala²,Glu⁴]deltorphin, DSLET, Met-enkephalin, Leu-enkephalin, β -endorphin, dynorphin A, dynorphin B, α -neoendorphin, heroin, hydromorphone, oxymorphone, levallorphan, codeine, hydrocodone, oxycodone and nalmefene.
- 31. (Original) The dosage form of Claim 30 wherein the drug is oxycodone.
- 32. (Withdrawn) The dosage form of Claim 30, wherein the drug is hydrocodone.
- 33. (Withdrawn) The dosage form of Claim 30, wherein the drug is oxymorphone.
- 34. (Withdrawn) The dosage form of Claim 30, wherein the drug is hydromorphone.
- 35. (Withdrawn) The dosage form of Claim 1 wherein the drug is a CNS depressant.
- 36. (Withdrawn) The dosage form of Claim 35 wherein the CNS depressant is a barbiturate.
- 37. (Withdrawn) The dosage form of Claim 35 wherein the CNS depressant is a benzodiazepine.
- 38. (Withdrawn) The dosage form of Claim 1 wherein the drug is a stimulant.
- 39. (Withdrawn) The dosage form of Claim 38 wherein the stimulant is selected from the group consisting of dextroamphetamine and methylphenidate.
- 40. (Withdrawn) The dosage form of Claim 1 wherein the drug is selected from the group consisting of immunosuppressants, anti-infectives, antioxidants, anesthetics, chemotherapeutic agents, steroids (including retinoids), hormones, antibiotics, sulfonamides, antiallergenics, desensitizing agents, vaccines, antivirals, antifungals,

antiproliferatives, antihistamines, decongestants, anticoagulants, antiphotoaging agents, melanotropic peptides, nonsteroidal and steroidal anti-inflammatory compounds, antipsychotics, radiation absorbers, miotics and anticholinesterases, parasympatholytics, sympatholytics, transquilizers, androgenic steroids, progestational agents, humoral agents, chemotherapeutic agents, antipyretics, antispasmodics, antimalarials, anti-nausea medication, cardioactive agents, nutritional agents, and natural and synthetic bioactive peptides and proteins.

- 41. (Original) The dosage form of Claim 1 wherein the drug is present in an amount from about 0.1mg to 1000mg.
- 42. (Original) The dosage form of Claim 1 wherein the drug is present in an amount from about 1mg to 500mg.
- 43. (Original) The dosage form of Claim 1 wherein the drug is present in an amount from about 2 mg to 250 mg.
- 44. (Original) The dosage form of Claim 1 wherein the drug is present in an amount from about 5 mg to 100 mg.
- 45. (Original) The dosage form of Claim 1 wherein the drug is present in an amount from about 5 mg to 50 mg.
- 46. (Previously Amended) The dosage form of Claim 1 wherein the dosage form delivers drug for a period of greater than 20 hours.
- 47. (Previously Amended) The dosage form of Claim 1 wherein the dosage form delivers drug for a period of greater than 12 hours.
- 48. (Previously Amended) The dosage form of Claim 1 wherein the dosage form delivers drug for a period of greater than 6 hours.
- 49. (Previously Amended) The dosage form of Claim 1 wherein the dosage form delivers drug for a period of greater than 4 hours.
- 50. (Previously Amended) The dosage form of Claim 1 wherein the dosage form delivers drug for a period of greater than 1 hour.
- 51. (Cancelled)
- 52. (Withdrawn) The dosage form of Claim 1 wherein the solvent comprises an alcohol.

53. (Withdrawn) The dosage form of Claim 1 wherein the solvent comprises an organic acid.

- 54. (Previously Amended) The dosage form of Claim 1 wherein the solvent comprises an organic acid derivative.
- 55. (Previously Amended) The dosage form of Claim 1 wherein the solvent comprises an organic acid ester.
- 56. (Currently Amended) The dosage form of Claim 1 wherein the solvent emprises possesses an alcohol and an organic acid residue.
- 57. (Previously Amended) The dosage form of Claim 1 wherein the solvent is selected from the group consisting of ethyl lactate (EL), triacetin, dimethyl sulfoxide (DMSO), propylene carbonate, N-methylpyrrolidone (NMP), ethyl alcohol, benzyl alcohol, glycofurol, alpha-tocoperol, Miglyol 810, isopropyl alcohol, diethyl phthalate, polyethylene glycol 400 (PEG 400), triethyl citrate, and benzyl benzoate.
- 58. (Previously Amended) The dosage form of Claim 1 wherein the solvent is present in an amount less than about 60% by weight.
- 59. (Original) The dosage form of Claim 58 wherein the solvent is present in an amount from about 20% to 50% by weight.
- 60. (Original) The dosage form of Claim 59 wherein the solvent is present in an amount from about 25% to 48% by weight.
- 61. (Original) An oral dosage form comprising a formulation comprising: SAIB,

CAB,

IPM,

EL, and

an opioid.

- 62. (Original) The dosage form of claim 61, wherein the SAIB, EL, IPM, and CAB having a butyryl content of around 36 wt%, an acetyl content of around 15.5 wt% and a hydroxyl content of around 0.8 wt% are present in a weight ratio of 65:27:3:5.
- 63. (Original) The dosage form of Claim 61 wherein the opioid is selected from the group consisting of alfentanil, allylprodine, alphaprodine, anileridine, apomorphine, apocodeine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, cyclazocine, cyclorphen, cyprenorphine, desomorphine, dextromoramide, dezocine, diampromide, dihydrocodeine, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxyaphetyl butyrate, dipipanone, eptazocine, ethoheptazine,

ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, heroin, hydrocodone, hydroxymethylmorphinan, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levallorphan, levorphanol, levophenacylmorphan, lofentanil, meperidine, meptazinol, metazocine, methadone, methylmorphine, metopon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, nalorphine, normorphine, norpipanone, ohmefentanyl, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenomorphan, phenazocine, phenoperidine, pholcodine, piminodine, piritramide, propheptazine, promedol, profadol, properidine, propiram, propoxyphene, remifentanyl, sufentanyl, tramadol, tilidine, naltrexone, naloxone, nalmefene, methylnaltrexone, naloxone methiodide, nalorphine, naloxonazine, nalide, nalmexone, nalbuphine, nalorphine dinicotinate, naltrindole (NTI), naltrindole isothiocyanate, (NTII), naltriben (NTB), nor-binaltorphimine (nor-BNI), betafunaltrexamine (b-FNA), BNTX, cyprodime, ICI-174,864, LY117413, MR2266. etorphine, DAMGO, CTOP, diprenorphine, naloxone benzoylhydrazone, bremazocine, ethylketocyclazocine, U50,488, U69,593, spiradoline, DPDPE, [D-Ala2,Glu4] deltorphin, DSLET, Met-enkephalin, Leu-enkephalin, \(\beta\)-endorphin, dynorphin A. dynorphin B, a-neoendorphin, or an opioid having the same pentacyclic nucleus as nalmefene, naltrexone, buprenorphine, levorphanol, meptazinol, pentazocine, dezocine, or their pharmacologically effective esters or salts, and combinations thereof.

- 64. (Original) The dosage form of claim 63, wherein the opioid is oxycodone.
- 65. (Withdrawn) The dosage form of claim 63, wherein the opioid is hydrocodone.
- 66. (Withdrawn) The dosage form of claim 63, wherein the opioid is oxymorphone.
- 67. (Withdrawn) The dosage form of claim 63, wherein the opioid is hydromorphone.
- 68. (Previously Amended) The dosage form of Claim 1, wherein the rheology modifier is isopropyl myristate (IPM).
- 69. (Original) The dosage form of claim 61, wherein SAIB is present in an amount ranging from about 50 wt% to about 80 wt%, ethyl lactate is present in an amount ranging from about 10 wt% to about 40 wt%, IPM is present in an amount up to about 10 wt%, and CAB is present in an amount up to about 10 wt%.
- 70. (Previously Amended) An oral dosage form comprising a formulation comprising a drug, a HVLCM, a network former, a rheology modifier, and a solvent, present in amounts effective to reduce the rate of extraction of the drug from the formulation with solvent while simultaneously providing desirable release kinetics of the drug upon administration to a subject.
- 71. (Original) The oral dosage form of claim 70, wherein the drug is an opioid.

72. (Original) The oral dosage form of claim 71, wherein the opioid is selected from the group consisting of oxycodone, hydrocodone, oxymorphone, and hydromorphone.

- 73. (Original) The oral dosage form of claim 70, wherein the network former is a CAB.
- 74. (Original) The oral dosage form of claim 70, wherein the rheology modifier is isopropyl myristate.
- 75. (Original) The oral dosage form of claim 70, wherein the reduced extraction rate occurs over a range of temperatures and concentrations.
- 76. (Original) The oral dosage form of claim 70, wherein the solvent is ethyl lactate.
- 77. (Original) A drug delivery device, comprising a formulation that, upon exposure to an aqueous environment, forms a network within the formulation and an outer surface.
- 78. (Previously Amended) A drug delivery device comprising a formulation comprising:

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a HVLCM;
a network former;
a rheology modifier;
a solvent; and
a drug.
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79. (Original) A drug delivery device comprising a formulation comprising:

SAIB, CAB,

IPM,

EL, and

an opioid.